# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	) Examiner: Kemmerer, Elizabeth
David BOTSTEIN, et al.	) ) Art Unit: 1646
Application Serial No. 09/992,643	) Confirmation No: 4960
Filed: November 14, 2001	) Attorney's Docket No. GNE-2730 P1C13
For: SECRETED AND TRANSMEMBRANE POLYPEPTIDES AND NUCLEIC ACIDS ENCODING THE SAME	) ) Customer No. 77845 )

FILED VIA EFS – MAY 13, 2008

### RESPONSE to NOTICE OF NON-COMPLIANT APPEAL BRIEF

### MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 32613-1450

Dear Sir:

This response to the Notice of Non-Compliant Appeal Brief, filed in connection with the above captioned patent application, is responsive to the Office communication mailed April 24, 2008.

Appellants enclose herewith, on pages 2-3 of this paper, an amended <u>SUMMARY OF</u>

<u>CLAIMED SUBJECT MATTER</u> which provides a summary of the claimed subject matter and refers to support for all independent claims on appeal, specifying by page and line number or paragraph number where such support may be found. This paper constitutes Appellants'

Response to the Notice of Non-Compliant Appeal Brief.

The substitute <u>SUMMARY OF CLAIMED SUBJECT MATTER</u> section on pages 2-3 of this paper will replace the SUMMARY OF CLAIMED SUBJECT MATTER which was originally filed in this matter.

<u>SUMMARY OF CLAIMED SUBJECT MATTER</u> begins on page <u>2</u>. <u>Remarks</u> begin on page <u>4</u>.

# V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention claimed in the present application is related to an isolated polypeptide comprising the amino acid sequence of the polypeptide of SEQ ID NO:207, referred to in the present application as "PRO1112." The amino acid sequence of the native "PRO1112" polypeptide and the nucleic acid sequence encoding this polypeptide (referred to in the present application as "DNA57702-1476") are shown in the present specification as SEQ ID NOs: 207 and 206, respectively, and in Figures 135 and 134, described on pages 294, lines 10-15. The full-length PRO1112 polypeptide having the amino acid sequence of SEQ ID NO:207 is described in the specification at, for example, on page 17, lines 14-18 and pages 127, lines 4-37 to page 128, lines 1-26. The isolation of cDNA clones encoding PRO1112 of SEQ ID NO:207 is described in Example 57, page 449, lines 1-29 of the specification.

The PRO1112 gene was shown for the first time in the present application to be significantly amplified in human colon and lung cancers as compared to normal, non-cancerous human tissue controls (Example 170, page 539, line 19 to page 5555, line 5; particularly Table 9A, pages 550-551). This feature is specifically recited in Claim 124, and carried by all claims dependent from Claim 124. In addition, the invention also claims the amino acid sequence of the polypeptide of SEQ ID NO:207, lacking its associated signal-peptide; or the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 209951 (Claims 124-126 and 129; see, e.g., page 127, lines 32-37 and page 128, lines 10-27). The invention is further directed to polypeptides having at least 80% to 99% amino acid sequence identity to the amino acid sequence of the polypeptide of SEQ ID NO:207; the amino acid sequence of the polypeptide of SEQ ID NO:207, lacking its associated signal peptide; or the amino acid sequence of the polypeptide encoded by the fulllength coding sequence of the cDNA deposited under ATCC accession number 209951, wherein the nucleic acid encoding said polypeptide is amplified in colon and lung tumors (Claims 119-123; see, e.g., page 127, lines 9-37 and page 128, lines 1-27)). The invention is further directed to a chimeric polypeptide comprising one of the above polypeptides fused to a heterologous polypeptide (Claim 130), and to a chimeric polypeptide wherein the heterologous polypeptide is an epitope tag or an Fc region of an immunoglobulin (Claim 131) (see, e.g., page 374, lines 24 to

page 375, line 9). PRO polypeptide variants having at least about 80-99% amino acid sequence identity with a full length PRO polypeptide sequence, or a PRO polypeptide sequence lacking the signal peptide are generally described in the specification at, for example, page 305, line 23 to page 308, line 6; and percent amino acid sequence identity determination is generally described at least at, for example, pages 306 line 14 to page 308 line 6. The preparation of chimeric PRO polypeptides (Claims 130 and 131), including those wherein the heterologous polypeptide is an epitope tag or an Fc region of an immunoglobulin, is set forth in the specification at page 374, lines 24 to page 375, line 9. Examples 140-143 and page 376, line 12 to page 378, line 6 describe the expression of PRO polypeptides in various host cells, including *E. coli*, mammalian cells, yeast and Baculovirus-infected insect cells.

Finally, Example 170, in the specification at page 539, line 19, to page 555, line 5, sets forth a 'Gene Amplification assay' which shows that the PRO1112 gene is amplified in the genome of certain human colon and lung cancers (see Table 9A, page 550-551). The profiles of various primary colon and lung tumors used for screening the PRO polypeptide compounds of the invention in the gene amplification assay are summarized on Table 8, page 546 of the specification.

#### REMARKS

Appellants provide an amended "Summary of Claimed Subject Matter" which includes additional references to the pages numbers and figures which disclose subject matter claimed in the pending application. Accordingly, Appellants submit that the present amended "Summary of Claimed Subject Matter" identifies all independent claims on appeal and refers to the specification by page and line number and to the drawings, to identify support for the pending claims in the application as originally filed.

#### **CONCLUSION**

For the reasons given above, Appellants submit that present specification clearly describes, details and provides a patentable utility for the claimed invention. Moreover, it is respectfully submitted that based upon this disclosed patentable utility, the present specification clearly teaches "how to use" the presently claimed polypeptide. As such, Appellants respectfully request reconsideration and reversal of the outstanding rejection of Claims 119-126 and 129-131.

The Commissioner is authorized to charge any fees which may be required, including extension fees, or credit any overpayment to Deposit Account No. <u>07-1700</u> (referencing Attorney's Docket No.GNE-2730 P1C13).

Respectfully submitted,

Date: May 13, 2008

JAMES A. FOX (Reg. No. 38,455)

GOODWIN PROCTER LLP

135 Commonwealth Drive Menlo Park, California 94025 Telephone: (650) 752-3100 Facsimile: (650) 853-1038